

Appl. No. : 10/005,684  
Filed : November 8, 2001

### REMARKS

Claim 1 has been amended. Claims 1-12 remain pending in the present application. Support for the amendments can be found in the specification and claims as filed. Accordingly, the amendments do not constitute the addition of new matter. Reconsideration of the application in view of the foregoing amendments and following comments is respectfully requested.

#### Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected Claims 1-6 under 35 U.S.C. § 112, second paragraph, as being indefinite. Regarding Claim 1, the Examiner objected to the terms "autoimmunity," "possible," and "normal." Claim 1 has been amended to recite "[a] method for distinguishing a likelihood of autoimmune disease from a likelihood of cardiovascular disease with autoimmune disease in a patient."

The term "autoimmunity" has been amended to "autoimmune disease."

The term "possible" has been amended to "likelihood." paragraph [0054] of the specification supports the use of the term "likelihood."

Regarding the term "normal," Claim 1 has been amended to recite "normal levels of said antibodies obtained from an average level of antibodies from a set of healthy control individuals." This amendment is supported by paragraph [0104] which defines the term "normal" as "an average level of antibodies from a set of healthy control individual." As stated in the previous Amendment, the results from the assay provide a diagnostic outcome. While it is true that a small number of individuals tested in the results shown in Figure 1 have antibody levels lower than those of healthy controls, this does not mean that the claimed assay does not provide a diagnostic outcome. The patients tested had known risk factors for autoimmune disease. One would expect a small number of those would not, in part, test positive for autoimmune disease. As amended, the term "normal" in Claim 1 is clear and definite by providing a definition of the term within the claim.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112, second paragraph.

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Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected Claims 1-12 under 35 U.S.C. § 112, first paragraph, because, according to the Examiner, the specification does not provide written description for the recited steps in Claim 1.

The recited steps in Claim 1 are supported by the specification, specifically in Example 9 and Figure 6. Claim 1 recites, *inter alia*, "a) determining a level of a first set of antibodies directed against a plurality of different antigens...in a sample from said patient;...b) determining a level of a second set of antibodies directed against a plurality of different antigens and/or corresponding recombinant antigens...in a sample from said patient; and c) comparing the level of antibodies determined in steps a) and b) with normal levels of said antibodies." Example 9 discloses obtaining levels of antibodies from patients against various antigens recited in Claim 1. Also, Example 9 refers to Figure 6 which provides a chart of correlation between reactivity of antibody to autoantigen and medical condition. Hence, all the steps of Claim 1 of "determining" levels of antibodies and "comparing" the levels of antibodies are delineated in Example 9. Thus, the recited steps of Claim 1 are fully supported by the written description of the specification.

The Examiner also rejected Claims 1-6 under 35 U.S.C. § 112, first paragraph, because, according to the Examiner, while the specification enables claims directed to a method for detecting antibodies against certain antigens and for indicating the presence or possibility of autoimmune disease, the specification does not provide enablement distinguishing possible autoimmune disease from possible cardiovascular disease with autoimmune disease.

Claim 1 has been amended to recite "[a] method for distinguishing a likelihood of autoimmune disease from a likelihood of cardiovascular disease with autoimmune disease in a patient." The disclosure showing support and enablement for this amendment can be found mainly in Example 9 and Figure 6. Figure 6 discloses distinguishing features of "possible autoimmunity" and "possible cardiovascular and autoimmune disease." Thus, amended Claim 1 recites a preamble that is fully supported the specification.

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The Examiner rejected Claims 1 and 3-9 because, according to the Examiner, the specification is not enabling for a method of detecting any and all antigens. Claim 1 has been amended to recite the antigens recited in Claims 2 and 12.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112, second paragraph.

### CONCLUSION

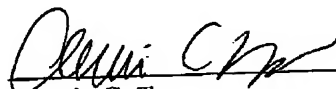
In view of the foregoing amendments and comments, it is respectfully submitted that the present application is fully in condition for allowance, and such action is earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully invited to call the undersigned in order to resolve such issue promptly.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By:   
Connie C. Tong  
Registration No. 52,292  
Agent of Record  
Customer No. 20,995  
(949) 760-0404

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